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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,367	08/01/2003	Paul V. Goode JR.	DEXCOM.016A	5134

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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06/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/633,367	Applicant(s) GOODE ET AL.	
	Examiner ROBERT L. NASSER	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-105, 176-181, 183-188 and 190-246 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 177, 184, 191, 203-208, 218-238 and 243-246 is/are allowed.
- 6) ☒ Claim(s) 85-105, 176, 178-183, 185-188, 190, 192-202, 209-217 and 239-242 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/9/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/2009 has been entered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86, 92, 94, 100-101, and 209-210 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the base claims were amended to recite that the sensitivity or the matched data pair is used to evaluate the stability, these claims now contradict the base claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85, 87-89, 91, 92, 95-97, 99, 100, 102-104, 176, 178-181, 183, 85-188, and 192-199 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al Say

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teaches a continuous glucose sensing device that includes a sensor data receiving module 96, a reference data receiving module 99 that receives reference data from a reference glucose sensor, a module that calibrates the sensor data using the reference data, and a stability determination module that determines that sufficient time after implantation has passed to allow the sensor to be stable (see column 44, lines 2-5). In column 44, it is clear that Say uses a reference point to calibrate a time corresponding sensor data point. Hence, it uses a matched data pair. In column 44, lines 46-54, Say discloses that the calibrated signal is compared before and after a new calibration point and that if the difference exceeds a threshold, recalibration is necessary, i.e. the system is not stable. Since the two glucose points are closely spaced in time, the any significant change in the values must be due to a change in the sensitivity. Hence, Say evaluates the stability based on the amplitude of the sensitivity. As to claim 87, Say only allows output after the calibration is deemed acceptable. Hence, the output is dependent on the stability. Claim 88 is rejected in that the output includes a glucose numerical estimate on a display. Claim 89 is rejected in that the reference module receives data from a glucose test (see column 43, lines 45-56). Claim 91 is rejected in that Say further teaches the method. As to claim 93, Say anticipates the claim in two ways. First, in column 44, line 30+, Say states that the output is stable if the signals from two working electrodes (one being a sensor and one being a reference sensor) are within a predetermined percentage of each other. The two values are then a matched data pair. Alternatively, Say states that it decides whether to keep the calibration point, presumably a matched data pair, based the uncalibrated sensor signal. Hence, Say is

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evaluating the reference and sensor data, i.e. deciding whether to keep the data. As such, it evaluates the a stability based on the matched data pair. Claims 95-97 are rejected for the reasons given above. Claims 99 and 102-104 are rejected for the reasons given above, noting that Say also teaches the system. Claim 178 is rejected in that Say has an alarm to warn the user of a current or upcoming hypoglycemic or hyperglycemic event (see column 45, lines 14-15). Claim 179 is rejected in that the system predicts future values (see column 55, line 2). Claims 180-181 are rejected in that the control system controls an insulin pump. Since the output occurs only after stability is reached, then the pump also is controlled only when a stability level is reached. Claims 185-188, 190, 192-202, 209-217, and 239-242 are rejected for the reasons given above.

Claims 90, 98, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al in view of Causey III, et al 6558320. In figure 5, Causey shows a reference monitor integral with the processing device. Hence, it would have been obvious to modify Shin to use such an integral reference monitor, as it is merely the substitution of one known reference monitor for another.

Claims 93, 175-177, 182-184, and 189-191 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 93 defines over the art in that none of the art evaluates stability based on the matched data pair, as claimed.

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Claims 175-176, 182-183, and 189-190 define over the art in that none of the art evaluates stability based on the sensitivity, as claimed.

Claims 177, 184,191, 203-208, 218-238, and 243-246 define over the art in that none of the art evaluates stability based on the oxygen, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
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June 8, 2009